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TITLE: Continuous Pre-Hospital Data as a Predictor of Outcome Following Major Trauma: A Study Using Improved and Expanded Data, Phase 2

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14. ABSTRACT This study was designed to acquire near continuous physiologic measurements, beginning at the earliest practical time after injury, on large numbers of injured patients with severe trauma. The study utilized commercially available FDA-certified monitoring equipment, operating in a fleet of ground EMS ambulances serving a large metropolitan area with multiple trauma centers. First Responders may represent the earliest opportunity to acquire medical data in injury cases. During Phase 2, research data was acquired and processed for 311 patients. This data will be correlated with significant clinical outcomes within the first 24 hours of admission and entered into a research database.Analysis demonstrated that the mean delay in onset of patient data acquisition within the ground EMS system was about half the mean delay for a random cohort of cases transported to the same hospitals by helicopter. Analysis also demonstrated a statistically significant difference between the two groups. Manufacturer updates for the monitor used by the participating fleet of ambulances were deployed between Phase 2 data collection operations, requiring research and adaptation of data processes. Anticipated improvements in efficiency and transparency of pre-hospital research data acquisition methods were not achievable during the phase 2 schedule.

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Introduction

This report is the Final Report for Phase 2 of the subject project, reporting on work described in the approved Statement of Work (SOW) for Phase 2 during the reporting period of January 23, 2004 through February 1, 2010. Phase 2 of the subject project began August 2, 2006, and the end date for Phase 2 is March 1, 2010 (research ends February 1, 2010).

The objective of this project is to develop, implement, test, and use a capability to collect relevant physiological and treatment data for seriously injured civilian trauma patients in support of the U.S. Army's "Combat Critical Care Engineering" (CCCE) research task area. The information that is needed includes pre-hospital physiological data for qualifying patients as well as post-arrival and outcome data.

This project represents one of the first attempts to accomplish these tasks in support of the CCCE program within a system of ground ambulances responding to incidents and caring for and transporting patients to Level 1 Trauma Centers. Ground Emergency Medical Services (EMS) represent the earliest practical opportunity, for most civilian traumatic injury cases, to begin acquiring needed patient data. This project builds upon the previous LifeLink mobile telemedicine project in San Antonio, Texas to accomplish these goals.

Phase 2 of the subject project resulted in the collection and processing of the target pre-hospital patient data for a total of 311 qualifying patient cases. The processed data and supporting documentation, with personally identifiable data deleted, was provided to U.S. Army Institute of Surgical Research (USAISR) for use in ongoing research programs. Case timing data was also collected for these cases to enable analysis relevant to the design of this study. The results of the case timing analyses on data collected during the subject project, as reported herein, show that ground EMS systems can provide patient data beginning significantly earlier in an injury event than patient data collectable within helicopter-based pre-hospital services. A summary of the case timing data and analysis for the initial Phase 2 data collection interval is presented in report section ***Task 2 Subtask 2d.*** A summary of case timing data and analysis for the Phase 2 second and third data collection intervals (combined) is presented in report section ***Task 4, Subtask 4d.*** Finally, a summary of comparative analysis of case timing data relevant to the goals of this study for all three Phase 2 data collection intervals combined, and comparison of case timing results between the initial Phase 2 data collection interval and Phase 2 second and third data collection intervals (combined) is also presented in report section ***Task 4, Subtask 4d.***

Body

Previous work on the subject project (Phase 1) was conducted to establish and use preliminary data collection capabilities in five San Antonio (SA) EMS ambulances operating within the LifeLink program and one receiving hospital. At that time, five participating SA EMS ambulances were using a data-capable physiological monitor (LifePak 12®) during pre-hospital patient care intervals. Southwest Research Institute® (SwRI®) worked with SA EMS, the USAISR, Brooke Army Medical Center (BAMC), the University of Texas Health Science Center at San Antonio (UTHSCSA), and Physio Control, Inc. (manufacturer of the LifePak 12® monitor) to establish required research protocols and approvals to facilitate the data collection and research operations, to operate the data collection system for one month, and to examine the

resulting data and draw preliminary conclusions about the capabilities of initiating pre-hospital data collection relatively early in qualifying trauma injury cases. As Phase 1 of the subject project was ending and Phase 2 was beginning, SA EMS began to replace the LifePak 12® physiological monitor, operating in a limited number of ambulances, with a new physiological monitor (MRx HeartStart®) manufactured by Philips Medical Systems. The new monitor was to be deployed in all ambulances operating within the SA EMS system.

Work began on Phase 2 of the subject project in early August 2006. The scope of work initially defined for Phase 2 of the project was primarily aimed at refining the process and expanding the capacity for data collection and to conduct data collection operations for one additional one-month interval. The initial work in Phase 2 included research focused on improving the efficiency and sustainability (automation) of acquisition of needed pre-hospital patient physiological data, building upon project work completed during Phase 1 using the LifePak 12® monitor. Two major components affecting this research and planning were (1) the data management capabilities of the monitor and (2) the logistical processes used within the SA EMS system relative to data collection. It was found that both of these "variables" were significantly affected by the introduction of the new monitor. The data collection and management capabilities of the new monitor were found to be limited and operator intensive, similar to the LifePak 12® monitor. In addition, it was discovered that the data management capabilities of the new monitor and the data management processes and procedures practiced by the SA EMS system were evolving, with changes and improvements in both variables planned for the near future. Based on significant interaction with the SA EMS system and Philips Medical Systems to better understand the current and evolving plans for the monitor capabilities and data management practices, SwRI submitted a request for a significant modification to the Phase 2 SOW. This request was submitted in mid-December 2006 and the modified Phase 2 SOW was formally approved in late February 2007.

The introduction of the new monitor and the placement of data-capable monitors in the entire fleet of ambulances in the SA EMS system provided opportunities for a greatly expanded volume of qualifying patient cases, resulting in a potentially much higher volume of data collection. Both the initial and the modified Phase 2 SOW included early work to research, plan, and develop data capture and logistical technical and efficiency enhancements (automation) for physiological monitor operations and SA EMS data collection processes. The modified Phase 2 SOW included an additional two (three total) planned one-month data collection intervals of operations, including an accelerated initial data collection interval using the existing (but limited) new monitor configuration and SA EMS processes and procedures adapted to the features of the new monitor. The first of the three planned data collection intervals was conducted soon after the approval of the modified Phase 2 SOW.

Work was planned in the modified Phase 2 SOW to integrate further improvements in future project data collection and processing operations with planned upgrades in capabilities and procedures for both the new monitor and the SA EMS system over the upcoming year. The two remaining data collection intervals planned for Phase 2 were intended to be coordinated with milestones in the evolving monitor and SA EMS system data management upgrades, yielding greater levels of automation and transparency in the acquisition of target project data. SA EMS, a cooperative project partner, however, experienced significant delays and changes in the planned patient data management upgrades during Phase 2 of the subject project.

After conduct of the initial Phase 2 data collection interval, SA EMS embarked on a program to upgrade all of the MRx monitors used by SA EMS to a newly released (by Philips Medical Systems) version of operating firmware. The firmware upgrade provided at that time did not include needed enhancements for the data management capabilities of the monitor related to the subject project and future plans for SA EMS data management capabilities. However, the firmware upgrade did affect the monitor's data file content and structure as developed and stored during patient care. SwRI researched the changes in monitor file structure and content and adapted procedures and processes to enable conduct of the planned Phase 2 second and third data collection intervals.

Efforts to synchronize project operations with the development of more automated and sustainable patient data collection capabilities within SA EMS were important to the overall goals of the project and were the subject of continuous interaction between SwRI and SA EMS during Phase 2. However, significant delays and changes in plans for relevant SA EMS data management upgrades continued. SwRI prepared to proceed with contingency plans as discussed in the proposal for the modified Phase 2 SOW. Under this scenario, SwRI began preparations for conduct of the remaining two planned patient data collection intervals, using essentially the same methods used during the initial data collection interval. This was done in order to assure completion of planned operations for the two remaining data collection intervals and completion of processing and providing the target patient data to USAISR within prevailing cost and schedule terms of the project.

Both the originally proposed and the modified SOW for Phase 2 included additional elements of work in support of enhanced data mining and visualization and follow-on efforts in research of improved remote diagnostic ultrasound image transmission and interpretability. The work planned for this task within the subject project involved limited coordination of access to facilities (LifeLink ambulance and communications system) to support research activities that were otherwise, generally, not within the scope of work for the subject project. Research tasks requiring these facilities, however, were not identified during Phase 2 of the subject project.

This section of the report presents discussion and significant accomplishments/problems encountered in the conduct of Phase 2 of the subject project. The section is organized to present this information as associated with relevant tasks and subtasks of the initially approved Phase 2 SOW and work following the approval of the modified Phase 2 SOW in February 2007. Efforts were made to focus early Phase 2 work on tasks that were consistent with the anticipated modification of the Phase 2 SOW (work common to both versions of the SOW). For Phase 2 tasks that included work prior to approval of the modified Phase 2 SOW, the task headings in the body of this report indicate mapping between relevant task headings in both the "initial award" and "modified" versions of the Phase 2 SOW. Additionally, a summary of comparative analysis of case timing data relevant to the goals of this study for all three Phase 2 data collection intervals combined, and comparison of case timing results between the initial Phase 2 data collection interval and Phase 2 second and third data collection intervals (combined) is presented in report section ***Task 4, Subtask 4d.***

PHASE 2 (initial award)

TASK 1. Implement improved field data collection process.

mapped to

PHASE 2 (modified)

TASK 1. To Develop and Implement Incremental Collection and Process Improvements.

Phase 2 (initial award)
Subtask 1.a Renew five additional project ambulances (ten total).
Subtask 1.c Implement semi-auto field data collection in five project ambulances.

Work on these elements of the initial Phase 2 SOW was delayed due to concerns about applicability of the tasks to the anticipated modification of the Phase 2 SOW. The evolving plan for deployment of a different physiological monitor and to place the new monitor in all of the ambulances operating in the SA EMS fleet affected plans for future data collection processes. These tasks to renew and implement improved data collection methods for five project ambulances were not included in the modified Phase 2 SOW.

Phase 2 (initial award)

Subtask 1.d Add University Hospital to the project (two hospitals total).

During Phase 1 operations of the subject project, USAISR worked with UTHSCSA and University Hospital to amend applicable research protocols, adding University Hospital as an additional data collection site. SwRI and SA EMS collaborated to include collection of pre-hospital data for patients transported by SA EMS to University Hospital in all Phase 2 operations.

Phase 2 (initial award)

Subtask 1.b Develop semi-automated field data collection system.

mapped to

Phase 2 (modified)

Subtask 1.a Collaborate with SA EMS and vendors to facilitate Trauma Vitals data content in developing data management procedures.

SwRI conducted numerous meetings and discussions with Philips Medical Systems, supplier of the new Philips MRx monitor, to explore current and planned capabilities for data transfer provided by the monitor and processing of monitor data facilitated by Philips' related software development kit.

Initial investigations of the MRx monitor revealed that the data management capabilities of the monitor were currently limited but were scheduled for upgrade. A similar situation existed with the monitor manufacturer's Software Developer's Kit (SDK) and compatible commercially available medical record products. There was currently little opportunity for collection of data by other than manual methods similar to the process used with the old monitor during the Phase 1 proof-of-concept data collection interval. Numerous manual operations were required to extract data for qualifying cases from the monitor memory after a qualifying transport was completed.

As the planned upgraded MRx monitor firmware was to become available in the future, however, SwRI planned to continue working with SA EMS and vendors of the monitor and reporting products to preserve data content needed for the CCCE program during future SA EMS routine medical records operations as reflected in the modified SOW for Phase 2.

SwRI also conducted numerous meetings with SA EMS to understand data collection technical and logistics issues and opportunities in system operations. Logistical issues relative to acquiring and collecting patient monitor data for qualifying cases in a large metropolitan EMS system are formidable. Collection operations that require special operations by paramedics in the field are problematic. SwRI and SA EMS examined procedural issues and the user interfaces and operations available within the MRx monitor in order to arrive at data acquisition and transfer concepts that could support practical manual field data collection operations.

SA EMS began work to implement early incremental features of the planned electronic case data system, and SwRI continued to work with SA EMS on these upgrades during Phase 2. The SA EMS electronic case data system was capable of accepting and storing manual entries by paramedics, filling in data fields in an electronic record, on a laptop computer. Data entries were confined to manual text and numerical entries in selected data fields for case and patient data and areas for case narrative, as manually entered by attending paramedics. The system was constructed around a commercial EMS database product provided by Zoll Data Systems, known as the Tablet PCR EMS data management product.

It was planned that the SA EMS electronic case data system would ultimately import and include physiological and event data stored in the MRx monitor during pre-hospital patient triage and care using the MRx monitor. However, SwRI found that the Tablet PCR–based electronic case data management system would be focused on producing case records that were compliant with the National EMS Information System (NEMSIS) standards. NEMSIS data standards reflect case summary reports designed to be efficient (for data storage) and would not include or preserve many of the data elements needed for the Army CCCE program. SwRI established contact with appropriate staff at Zoll Data Systems to address this concern. SwRI and the Medical Director for SA EMS teamed to work with Zoll Data Systems to reinforce the need to preserve raw data content acquired through use of the MRx monitor. SwRI and the SA EMS Medical Director emphasized the need to also retain the raw MRx monitor data files for each case in order to facilitate retrospective in-depth case review as part of SA EMS operations and quality control, and to facilitate future retrospective research, as needed for the CCCE program. Zoll Data System's response to these requests included plans to preserve the raw monitor data files for each case in compressed form, to be imported and stored with the more general case summary reports, in the SA EMS electronic case data system. This step would facilitate more transparent and efficient future collection and retention of subject study research data and also support future retrospective in-depth case review during routine EMS operations.

The planned development and rollout of the SA EMS electronic case data system included plans for a wireless (bluetooth) link between the MRx monitor and the paperless (laptop-based) case reporting system used by each EMS crew in the field. The wireless link approach would provide an opportunity for the SA EMS crew to "near autonomously" extract patient physiological data acquired by the MRx monitor, for each case, and import the patient physiological data into the onboard laptop computer electronic records system. The case summary reports developed within the onboard laptop system, and containing electronic and manually entered (by the crew) case

information, would remain stored within the onboard laptop computer until a later time, at which time the population of recent case files stored on the onboard laptop would be imported into the SA EMS electronic case data system mainframe computer for further processing and storage. The electronic MRx monitor data would be further processed by the Tablet PCR product within the onboard laptop computer to produce and store the planned NEMSIS-compliant case summary report. As reported above, SwRI intervened to help arrange for each case summary report to also preserve and retain compressed versions of the raw MRx data files, usable for retrospective detailed analysis and research. The goal of this work by SA EMS was to facilitate more comprehensive and efficient case summary reporting in electronic format, including electronic storage, maintenance, and access for case summary reports using a dedicated system database.

The Phase 2 project plan included steps to coordinate enhancements in transparency and efficiency for patient pre-hospital research data collection in support of the CCCE Trauma Vitals program. These advancements were to be enabled by incremental development, rollout, and routine use of the SA EMS electronic case data system. SwRI continued working with SA EMS, Philips Medical Systems, and Zoll Data Systems to identify opportunities for integration of more efficient and more transparent (to EMS operations) collection of patient data needed for research purposes, as operational improvements in the SA EMS electronic case data system were implemented and rolled-out for routine use in EMS operations. The first candidate enhancement that was identified focused on use of the wireless link between the MRx monitor in each ground ambulance and the on-board EMS crew laptop to achieve extraction of, and access to, electronic monitor patient data. This was an important incremental step in the desired ultimate methodology for access and extraction of qualifying research case data from future routine data operations planned by SA EMS.

Philips Medical Systems achieved an initial release of the MRx monitor data management upgrade firmware module and supporting case review software products in late CY2007. Zoll Data Systems and Philips Medical Systems concluded a licensing agreement in CY2008, to facilitate planned further development of the Zoll Tablet PCR system to accommodate import of MRx monitor electronic patient data records for use in the electronic case data system. At the conclusion of Phase 2, this product had not been fully implemented and the SA EMS capability to incorporate patient electronic physiological data provided by the Philips MRx monitor within case records remained under development.

Phase 2 (initial award)

Subtask 1.b Develop semi-automated field data collection system.

mapped to

Phase 2 (modified)

Subtask 1.b Integrate and adapt evolving monitor and EMS data management in Trauma Vitals pre-hospital patient data collection.

SwRI developed data processing algorithms to be used in extracting and formatting patient case data provided by the MRx monitor that was in use by the SA EMS system. This work was based on SwRI's understanding of the content and format of relevant data within the case files produced by the MRx monitor. The raw files containing relevant patient data are produced and

stored within the monitor during patient care and were extracted from the monitor retrospectively for project data collection purposes. SwRI-developed algorithms organize the data into reports containing content and formatting usable by the CCCE program. The algorithms also read and process embedded case timing information to facilitate case association and case timing analysis. The specially developed algorithms are also capable of organizing variable strings representing digitally sampled physiological waveform data into comma separated variable files, which facilitate the use of experimental signal processing and validation techniques.

SwRI investigated the results of numerous sample data conversions using sample data acquired by employing an MRx monitor on un-identified paramedic volunteers. The processing algorithm investigations were conducted interactively as a number of questions were answered through contact with the monitor manufacturer or by project research and investigations. A number of refinements to the structure and operation and operator interfaces were also incorporated during the development of the process algorithms. SwRI also conducted investigations and research to answer data- and format-related questions arising from the developing data process techniques and validated the algorithm output by comparison of selected output data against the output of commercially available case reporting software provided by the monitor manufacturer. It was anticipated that SwRI would soon begin processing data collected for multiple actual civilian trauma cases acquired in a dynamic, stressful, and sometimes chaotic environment during field care and transport of seriously injured patients. SwRI continued development and refinement of the data processing algorithms during Phase 2 as variability in procedural and case anatomy were encountered during data collection operations.

Phase 2 (initial award)

Subtask 2.b Collaborate with ISR on Trauma Vitals data research and data mining and visualization methods.

mapped to

Phase 2 (modified)

Subtask 1.c Support and collaborate with ISR on Trauma Vitals data research objectives and data mining and visualization methods.

SwRI conducted initial meetings with USAISR to begin to understand current and planned data research capabilities and approaches at USAISR within the CCCE project. SwRI presented a number of data mining, processing, and visualization concepts that have been derived from previous work not related to the subject project.

SwRI continued development and refinement of special data processing algorithms, based on templates and other input provided by USAISR, to provide needed patient monitor data in Extensible Markup Language (XML) data files with data content and format suitable for import into the CCCE program Trauma Vitals database.

The raw MRx monitor data files that contain relevant patient data are produced and stored within the monitor during patient care and are extracted from the monitor retrospectively for project data collection purposes. The physiological data files for each patient care interval begin when the monitor is turned on, and are closed and stored within the monitor's internal memory when

the monitor is turned off. After completion of Task 2 of the subject project, all of the Philips MRx physiological monitors used by SA EMS were upgraded with new versions of operating firmware. During preparations for conduct of SOW Tasks 3 and 4, SwRI and SA EMS collaborated to acquire trial raw data files from current MRx monitor devices for pre-operational testing and analysis of SwRI data processing algorithms. SwRI found that the structure and content of the data files produced by the monitor during patient care was altered pursuant to the monitor firmware upgrade. SwRI continued interaction with SA EMS and Philips Medical Systems (supplier of the MRx monitor) and reacted to these changes by modifying SwRI patient data processes, as needed, to produce patient data files usable within the Trauma Vitals database.

The improved data extraction algorithms developed by SwRI are also capable of extracting and processing embedded monitor start, stop, and event time information. This information is used to facilitate organization of the needed XML data files for each case, and to facilitate association of each monitor case file and case records developed by SA EMS during each injury response case. The extracted monitor start, stop, and event time data also enable case timing analyses relevant to the goals of the subject study.

SwRI conducted meetings with USAISR during Phase 2 of the subject project to better understand current and planned data research capabilities and approaches at USAISR within the CCCE project and to discuss questions and new ideas regarding analysis and interpretation of data within the research database.

PHASE 2 (initial award)

TASK 2. Continue/expand collection and research of EMS Trauma Vitals data.

mapped to

PHASE 2 (modified)

TASK 2. To Conduct First Data Acquisition Interval – Manual Data Collect Methods.

Phase 2 (initial award)

Subtask 1.b Develop semi-automated field data collection system.

mapped to

Phase 2 (modified)

Subtask 2.a Develop operational procedures; prepare, train, and coordinate with EMS.

SwRI initiated renewal and/or modification of planned sub-awards and agreements to facilitate continuation of data collection and processing operations in Phase 2. This included consulting agreements for off-time data collection operations by selected SA EMS paramedics and staff, consulting for case association and analysis by the Medical Director for SA EMS, and provisions for research nurse work at USAISR in collecting and processing in-hospital data for relevant qualifying cases for the CCCE program.

SwRI coordinated and planned with SA EMS to establish procedures and processes for manually identifying candidate qualifying cases (code 3 adult trauma cases) and to acquire the raw MRx case data files and corresponding SA EMS run-sheet and patient care forms (without personal identifying information) for the identified cases.

The case selection process for the initial Phase 2 data collection interval was focused on identification of all code 3 injury cases handled by the SA EMS system during the operational period. This information was gathered by frequent sort and review queries on SA EMS dispatch and case records. Further evaluation was required to exclude cases that did not fit the qualified study population.

Information available from the SA EMS dispatch and case records included identification of the unique SA EMS unit that responded in the case of interest in addition to an assigned seven-digit SA EMS system case number, date and time information, and case disposition information. The SA EMS seven-digit case number was used to coordinate further work to acquire electronic monitor data with SA EMS, as personally identifiable information was not available.

The patient physiological data collection process required physical access to each ambulance that was involved in each of the identified candidate cases, retrospectively, in order to gain access to the physiological monitor that was in use during the identified case. The raw data files for candidate cases were then manually selected, based on case time and date information, and extracted from the monitor internal memory and stored on a portable memory card.

SwRI continued development and refinement of algorithms used in extracting and storing the collected raw MRx case data files from monitor memory cards. The MRx monitor files, as stored on the monitor memory card, were labeled with an encrypted alpha-numeric eight-character label and were not readily associable with identified qualifying case time, location, or EMS unit number information. SwRI developed special data transfer algorithms, deployed on a research data acquisition laptop computer, which provided the user with extracted SA EMS unit number and monitor start date and time information for each of the raw MRx data files. Once this "case identifier" information was compared with the previously identified candidate qualifying case list, the algorithm provided a prompt to the operator to initiate automatic data transfer from the memory card to the laptop PC. The data transferred to the data acquisition laptop was organized by time and date of the data transfer session from the memory card to the laptop, and the raw MRx case data files were stored within folders labeled with SA EMS unit number and monitor start date and time. SwRI coordinated with consulting SA EMS staff and data collection personnel throughout the data collection interval on refinements to the case identification and data extraction and transfer process.

Subtask 2.b Conduct collection operations for one month, all SA ambulances, two hospitals.

SwRI and SA EMS began field operations for the first planned Phase 2 patient data collection interval on April 1, 2007 and continued operations through May 3, 2007. During this period, data usable within the Trauma Vitals database for 102 qualifying patients was collected and processed. These data demonstrate an average rate of qualifying code 3 injury patients cared for and transported across the SA EMS organization of about three patients per day. This level of

operations reflects a significantly high volume of cases for which needed research data can be acquired.

Data collected retrospectively from monitors used in patient care for identified cases was stored on portable memory cards compatible with the MRx monitor. SwRI and SA EMS collaborated continuously during the period of operation to identify and evaluate cases and to transfer acquired electronic monitor data to the SwRI data acquisition laptop PC for temporary storage. The data collected included digital physiologic parameter and digitally-sampled waveform data files along with associated monitor serial number, operational data, events, and times. No personally identifiable information was included in the electronic files.

As the field monitor data collection work proceeded, SwRI and SA EMS also collaborated to collect run-sheets and patient care forms for each case, as routinely generated during SA EMS operations, for identified cases and with personally identifiable data deleted. Information obtainable from these forms included the SA EMS 7-digit case number assigned to each case, the unique unit number of the ambulance(s) dispatched for the case, the age of the patients (s) involved, the general type of incident involved, the hospital(s) receiving the patient(s), and the date and time of the EMS 911 call, time of the EMS unit arrival at the scene, and time of EMS unit arrival at the receiving hospital.

Subtask 2.c Review and upgrade SwRI Trauma Vitals data process algorithms relative to developing data content.

During conduct of the first of the three planned one-month data collection intervals for Phase 2, SwRI, working with SA EMS, accessed patient physiological data acquired using the new MRx monitor during patient care and transport retrospectively for each identified candidate patient. SwRI continued work to enhance the utility and accuracy of the special data processing algorithms based on experience gained during the data collection interval. SwRI also researched and identified process improvements to aid in accuracy of case timing and association efforts. SwRI continued to research content and format related questions arising from the developing data process techniques. SwRI continued to use commercially available case reporting software, provided by the monitor manufacturer, to validate data process conversion and output, through comparison of selected output of the commercial product against the output of SwRI-developed data processing tools focused on the needs of the Trauma Vitals database and the CCCE program. SwRI anticipated that further refinements for the data processing algorithms would be identified and addressed as more experience was gained in processing data acquired during sometimes stressful environments and encountering un-anticipated variables during EMS field operations.

It is notable that some SA EMS case files were encountered during the initial Phase 2 data collection interval which included information for multiple patients. This event arises when multiple trauma victims are associated with a single incident. Typically, each code 3 trauma patient is cared for and transported by different responding ambulances. SA EMS case records, however, are developed around incidents as initiated by the 911 call for help. Therefore, SA EMS case files can include information for multiple patients associated with a particular incident.

It is also notable that some candidate patient cases were encountered during the initial Phase 2 data collection interval for which the patient was triaged and cared for in the field by SA EMS but the patient was ultimately transported to a hospital by air helicopter services. This typically occurs when a particularly emergent trauma case is encountered and current traffic or other conditions impact the ability to effect a quick transport of an injured patient to a hospital by ground systems. For qualified patients in this category, electronic pre-hospital physiological data acquired during the early ground care (first responder) interval of the case was collected and processed as described herein, and the resulting Trauma Vitals research data and case information was noted to reflect the ultimate air transport for the respective case. If research electronic pre-hospital patient data was being collected within the respective helicopter service, events such as this may provide an opportunity to merge electronic pre-hospital patient data collected during the early first responder ground care interval and the following helicopter-based care and transport interval to produce research data records spanning the combined intervals.

Candidate patient cases were also encountered during the initial Phase 2 data collection interval where multiple electronic monitor files were generated during SA EMS care and transport of a single patient. This occurs when the monitor in use is turned off and restarted during the pre-hospital interval, such as would happen if the monitor batteries become depleted and need to be replaced with spare charged batteries.

Subtask 2.d Associate cases, process, and provide pre-hospital patient data to ISR.

In order to develop the desired research data, SwRI needed to accurately associate identified SA EMS qualifying patient case information with the appropriate electronic digital data files generated by the MRx monitor. This needed to be accomplished without availability of patient personally identifiable information within the records or files.

Responding SA EMS unit number identification and date and time information for each case was derived from SA EMS case records during work to identify potentially qualifying cases for patient data collection. Electronic data files produced for each case using the MRx monitor include unique monitor serial number information within the contents of the data files. In order to accurately accomplish retrospective association between identified qualifying SA EMS case records and electronic data files extracted from the MRx monitors used during patient care and transport by SA EMS, it was useful to correlate individual SA EMS units and the monitors on board the units. This provided confirmation that electronic monitor files under examination for a particular case of interest were correctly linked to the individual SA EMS unit involved in the case.

In order to confirm which MRx monitor files were associated with each SA EMS unit, it was necessary to track the monitor identification (serial number) assigned to each SA EMS unit. A list of EMS units and corresponding MRx monitor serial numbers was compiled to help with this issue; however, the matching of EMS unit number and monitor serial number was subject to change during the data collection interval. Such changes were usually the result of an SA EMS crew encountering a problem in the use of an assigned monitor and temporarily replacing the suspect monitor with one from a pool of spare monitors until the assigned monitor was returned to service. SwRI and SA EMS collaborated to deal with these variables by including all available spare MRx monitors in the list of monitors used by SA EMS and vigilantly tracking the movement of spare monitors as deployed to EMS units in the field.

Further association between electronic data files extracted from the MRx monitor used in patient care and transport and the SA EMS case record for a case of interest was achieved by examining the date and time of the beginning of the electronic files developed within the monitor during use. The monitor session times contained within electronic files were correlated with the SA EMS records including date and times for the relevant 911 call for help, SA EMS dispatch time, and time of arrival of the SA EMS unit on the scene.

Data files within the monitor memory begin at the time the monitor is turned on and are terminated and stored as the monitor is turned off. The monitor is capable of displaying (on the monitor screen) a list of file folders containing data stored for each monitor operation interval that is labeled with the date and time that the monitor was turned on for each interval. The MRx monitor places start, stop, and event time data within each electronic file generated and stored during use. The time information included in the monitor record is derived from an internal clock, which is not automatically synchronized with the SA EMS dispatch and case tracking system clock. This issue was found to be a source of potential errors or uncertainty in case association and development of case timing relationships for the first few cases for which patient data was collected and processed. SwRI and SA EMS adopted procedures to check the monitor clock setting each time a monitor was accessed for data collection and note time differences between the monitor internal clock and the system clock, and to then synchronize the monitor clock with the system clock if needed. This procedure provided information needed to assess the accuracy of relative timing between events found in the monitor electronic data and the SA EMS case run-sheets and case summary forms for identified qualifying cases, and to apply retrospective corrective factors if needed.

Finally, all electronic files extracted from MRx monitors during the data collection interval were imported into commercially available case summary reporting software provided by Philips Medical Systems, the manufacturer of the MRx monitor. While this tool did not process or retain much of the information required for use in the Trauma Vitals database, it was a useful tool for confirmation of accurate association of SA EMS cases of interest and electronic data files obtained retrospectively from the MRx monitors. The tool displayed a list of the MRx monitor files entered, including the monitor serial number, an encrypted case identifier number, the date and time of the beginning of the operation interval, and other information. The tool provided the ability to review the list of cases as a group, sorted by chronological order or by monitor serial number, which was correlatable to a unique SA EMS unit. The ability to examine this summary information for a group of electronic monitor files collected during an increment of time was helpful in cross-checking and confirming case associations based on individual file examination, and in detecting and resolving unusual events such as multiple electronic monitor files generated for a single patient, multiple patients listed within a single SA EMS case file, and manual entry errors or inconsistencies.

The data files collected from the monitor used in the respective EMS unit for an identified qualifying case were typically a set of three to six monitor file folders labeled (on the monitor display) with start times near the anticipated monitor start time, based on knowledge of the SA EMS unit dispatch time and time of arrival at the scene for the identified candidate case. Electronic monitor files found not to associate with identified qualifying cases were not processed and were deleted from the records.

During the Phase 2 initial data collection interval, SwRI and SA EMS identified 109 code 3 injury/trauma cases for data collection and processing for the subject study. During retrospective analysis, nine patient records were excluded from the study because it could not be established that the patients met age criteria for the subject study. An additional two patient records were excluded from the study because accurate association between the respective SA EMS case records and electronic monitor files could not be adequately established. Excluded cases were not further processed and respective data were discarded. In two cases, two electronic monitor files were generated within the MRx monitor for the same patient and were collected and processed accordingly. In four of the SA EMS case records, two patients were cared for and transported by different SA EMS ambulances, due to injuries sustained in the same incident (same SA EMS case). Therefore, SwRI provided a total of 104 processed data files for use in the Trauma Vitals database, reflecting pre-hospital data acquired for 102 qualifying patients.

SwRI provided the electronic pre-hospital data for the 102 qualifying patients as processed for use in the Trauma Vitals database to USAISR. Also, the respective SA EMS run-sheets and patient care forms that were acquired during the Phase 2 initial data collection interval, without personally identifiable information, were also provided to USAISR for use in the CCCE research program.

In addition to providing relatively high volumes of data for the CCCE research program, the subject study was also focused on beginning pre-hospital patient data acquisition as early in an injury event as practical. Analysis relevant to the design of the subject study included timing analyses for qualifying cases for which patient pre-hospital data was collected and processed and ultimately provided for further research purposes. The Initial Data Delay (IDD), which is defined as the time delay between an injury event and the beginning of acquisition of the pre-hospital monitor electronic data for research purposes, was derived from date and time information contained in the SA EMS run-sheet and patient care form records and similar information contained within the respective electronic monitor files.

As previously reported, during Phase 1 of the subject study, a limited pre-hospital patient data collection interval was conducted using a different monitor and a fraction of the ambulances operating in the SA EMS system. Timing analyses were conducted for the 25 qualifying cases encountered during the Phase 1 ground EMS data collection interval and for a random cohort of 57 qualifying cases transported to participating San Antonio Level 1 Trauma Centers by helicopter services. Collaborative comparative analyses by SwRI and USAISR demonstrated that, for these samples, the Mean Initial Data Delay (MIDD) time value for the helicopter services was almost 15 minutes longer than the MIDD experienced by the ground SA EMS first responder system. Further analysis of the variances between the two data sets demonstrated a statistically significant difference between the two groups ($p<0.05$).

Similar analyses were conducted for the pre-hospital patient data acquired during the initial Phase 2 data collection interval. For this data population of 102 qualifying patient cases, the MIDD experienced by the ground EMS first responder system was shorter (approximately 17.5% less delay) than the MIDD obtained during the limited Phase 1 interval. For comparative analyses of IDD data as reported for Phase 2, an onpaired, two tailed Student's t-test was applied to assess differences between groups using Excel (Microsoft 2007). P-values < 0.05 were considered significant. Comparative analysis between the MIDD obtained during the Phase 2 initial ground EMS collection interval and the MIDD for the previous random cohort of cases

transported by helicopter services showed that, for these samples, the ground EMS first responder services experienced a MIDD almost 19 minutes shorter than the MIDD experienced by the helicopter services. Further analysis of the variances between the two data sets demonstrated a statistically significant difference between the two groups ($p<0.05$). A summary of statistical values derived from analysis of the two data populations is presented in Table 1. Data from this analysis are graphically presented as means ± standard deviation in Figure 1. Table 1 contains minor corrections for two typographical errors discovered in interim reporting for the subject project. Errors found in previously reported versions of the table for the comparative time difference (Δ=Gnd-Air [absolute value]) for the standard deviation and the range of the two study populations have been corrected in Table 1.

Table 1. Statistical Summary of Initial Data Delay Times for Air and Ground Services; Phase 2 Initial Ground EMS Data Collection Interval

	Ground EMS Service Phase 2, 1st Interval (n=102); (hr:min:sec)	Helicopter Service (n=57);(hr:min:sec)	Δ=Gnd-Air (abs. val.) (hr:min:sec)
MIDD	00:19:11	00:37:59	00:18:48
Standard Deviation	00:06:46.4	00:19:34.8	00:12:48.4
Range	00:35:44	01:28:41	00:52:57
95% Confidence Interval Upper Bound	00:20:30	00:43:11	00:22:41
95% Confidence Interval Lower Bound	00:17:52	00:32:48	00:14:56

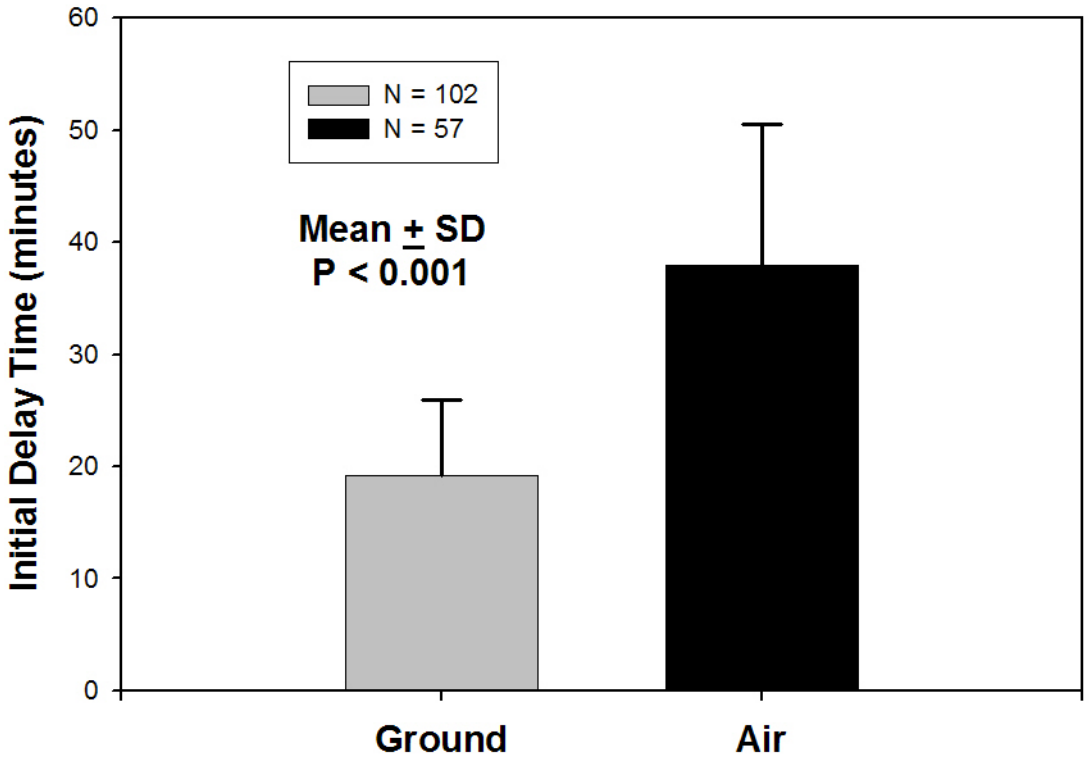

Figure 1. IDD Analysis Results; Phase 2 Initial Ground EMS Interval Compared to Helicopter Experience

For these samples, the helicopter data began 98% (MIDD) later than the ground EMS system after the estimated time-of-injury.

TASK 3. To Conduct Second Data Acquisition Interval – Improved Manual Data Collect Methods.

Subtask 3.a Develop operational procedures; prepare, train, and coordinate with EMS.

As described in the introduction section of this report, SwRI implemented contingency plans for conduct of the second Phase 2 data collection interval of the subject project. SwRI and SA EMS collaborated to conduct the Phase 2 second data collection interval using similar manual methods as developed and used in the Phase 2 initial data collection interval. SwRI continued coordination and planning with SA EMS related to procedures and processes for identification of candidate qualifying cases (code 3 adult trauma cases) and for acquisition of relevant raw MRx monitor case data files and related SA EMS run-sheets and patient care forms (without personal identifying information) for the identified cases.

Additional operating and standby ambulances were added to the SA EMS fleet between conduct of the first and second data collection intervals. Also, assignments of MRx physiological monitors in use by the SA EMS were adjusted during this time. A larger pool of spare monitors was established by SA EMS and spare monitors were deployed as needed to operating SA EMS units when an assigned monitor was found to require service. SwRI adapted the specially

developed data transfer algorithms, deployed on the research data acquisition laptop computer, which provided the user with extracted SA EMS unit or spare monitor number and monitor start date and time information for each of the raw MRx data files that were acquired.

Coordination, training, and preparation work between SwRI and SA EMS was conducted similar to that reported for the initial Phase 2 data collection interval.

Subtask 3.b Conduct collection operations for one month, all SA ambulances, 2 hospitals.

SwRI and SA EMS began field operations for the second planned Phase 2 patient data collection interval on April 1, 2009 and continued operations through April 30, 2009. During this 30 day period, data ultimately usable within the Trauma Vitals database for 48 qualifying patients was collected.

Data was collected during the second Phase 2 data collection interval retrospectively from monitors used in patient care for identified cases and was stored on portable memory cards compatible with the MRx monitor as described for the initial Phase 2 data collection interval. SwRI and SA EMS collaborated continuously during the period of operation to identify and evaluate cases and to transfer acquired electronic monitor data to the SwRI data acquisition laptop PC for temporary storage. The data collected included digital physiologic parameter and digitally-sampled waveform data files along with associated monitor serial number, operational data, events, and times. No personally identifiable information was included in this data.

As the field monitor data collection work proceeded, SwRI and SA EMS also collaborated to collect case run-sheets and patient care forms, as routinely generated during SA EMS operations, for identified candidate cases, with personally identifiable data deleted. Information obtainable from these forms includes the SA EMS seven digit case number assigned to each case, the unique unit number of the ambulance(s) dispatched for the case, the age of the patients (s) involved, the general type of incident involved, the hospital(s) receiving the patient(s), the date and time of the EMS 911 call, time of the EMS unit arrival at the scene, and time of EMS unit arrival at the receiving hospital.

Subtask 3.c Review and upgrade SwRI Trauma Vitals data process algorithms relative to developing data content.

SwRI continued work to enhance the utility and accuracy of the special data processing algorithms based on experience gained during the initial Phase 2 data collection interval. During the time between completion of the Phase 2 initial data collection interval and the start of preparations for conduct of the Phase 2 second data collection interval, all of the Philips MRx physiological monitors used by SA EMS were upgraded with revised operating firmware. SwRI continued interaction with SA EMS and Philips Medical Systems (supplier of the MRx monitor) to react to changes in the monitor data output files by modifying and testing SwRI patient data processes as needed to produce patient data files usable within the Trauma Vitals database.

SwRI also researched and identified process improvements to aid in accuracy of case timing and association efforts. SwRI continued to research content and format related questions arising from the developing data process techniques. SwRI continued to use commercially available case reporting software, provided by the monitor manufacturer, to validate data process conversion and output, through comparison of selected output of the commercial product against the output

of SwRI-developed data processing tools focused on the needs of the Trauma Vitals database and the CCCE program.

One of the candidate SA EMS cases encountered during conduct of the second Phase 2 data collection interval included patient care and transport of two qualifying patients, as more completely described for the initial data collection interval. Electronic monitor data and related SA EMS run-sheets and patient care forms were identified and collected for both patients that were associated with the same SA EMS case number

Subtask 3.d Associate cases, process, and provide pre-hospital patient data to ISR.

In order to develop the desired research data, SwRI needed to accurately associate identified SA EMS qualifying patient case information with the appropriate electronic digital data files generated by the MRx monitor. This needed to be accomplished without availability of patient personally identifiable information within the records or files. These operations were conducted as described above for the initial data collection interval conducted during Phase 2.

During the Phase 2 second data collection interval, SwRI and SA EMS identified 75 candidate cases for data collection and processing for the subject study. During collection operations, data for eight of the identified cases were not collectable as the target case data had been overwritten by new case data within the subject SA EMS monitors. SwRI and SA EMS operated to collect and process electronic monitor data for 67 code 3 injury/trauma cases identified as candidates. During retrospective analysis, 20 cases were excluded from the study because it could not be established that the patients met age criteria for the subject study, because an accurate association between the respective SA EMS case records and electronic monitor files could not be adequately established, or because corrupted electronic data files were encountered during processing. Excluded cases were not further processed and respective data were discarded. For one case, two patients were cared for and transported by different SA EMS ambulances, due to injuries sustained in the same incident (same SA EMS case). Therefore, SwRI provided a total of 48 processed data files for use in the Trauma Vitals database, reflecting pre-hospital data acquired for 48 qualifying patients.

SwRI provided the electronic pre-hospital data for the 48 qualifying patients as processed for use in the Trauma Vitals database to USAISR. Also, the respective SA EMS run-sheets and patient care forms that were acquired during the Phase 2 second data collection interval, without personally identifiable information, were also provided to USAISR for use in the CCCE research program.

Case timing data and associated analyses relevant to the goals of the subject study were combined for Phase 2 Task 3 (second of three planned Phase 2 data collection intervals) and Phase 2 Task 4 (third of three planned Phase 2 data collection intervals). A summary of the acquired case timing data and analysis results for data collected during Task 3 and Task 4 combined is presented in ***Task 4, Subtask 4d*** of this report.

<u>TASK 4.</u> To Conduct Third Data Acquisition Interval – Integrated with EMS Operations.

Subtask 4.a Develop operational procedures; prepare, train, and coordinate with EMS.

As described in the introduction section of this report, SwRI implemented contingency plans for conduct of the third Phase 2 data collection interval of the subject project. SwRI and SA EMS

collaborated to conduct the Phase 2 third data co llection interval using sim ilar manual methods as developed and used in the first and second ph ase 2 data collection inte rvals. SwRI continued coordination and planning with SA EMS related to procedures and processes for identification of candidate qualifying cases (code 3 adult traum a cases) and for acqu isition of relevant raw MRx monitor case data files and SA EMS run-sheet and patient care form data (without personal identifying information) for the identified cases.

During conduct of the second and third planned data collection in terval for Phase 2, it became apparent that the num ber of qualifying cases fo r which pre-hospital phy siological and related case information data could be collected was lo wer than the anticipate d 100 cases per interval. SwRI and SA EMS collaborated to extend data collection operations in order to acq uire data for the anticip ated num ber of cases. Therefore, th e Phase 2 third da ta colle ction inte rval was actually conducted as two sub-inte rvals, identified as interval 3a and interval 3b. SwRI and SA EMS continued preparations and coordination for the conduct of data collection intervals 3a and 3b in similar fashion as that described for the phase 2 second data collection interval.

Subtask 4.b Conduct collection operations for one month, all SA ambulances, two hospitals.

SwRI and SA EMS began field operations for the third planned Phase 2 patient data collection interval (interval 3a) on Ma y 1, 2009 and continue d operations through May 31, 2009. During this 31 day period, data ultim ately usable within the Traum a Vitals database for 87 qualifying patients was collected. The extended Phase 2 thir d da ta co llection inte rval (interval 3b) was conducted between No vember 1, 2009 and Decem ber 15, 2009. During in terval 3b, data ultimately u sable with in the Trauma Vitals da tabase f or 74 qualif ying patien ts was colle cted. Combining these sub- intervals, 161 qualifying patient cases ultim ately usable in the Traum a Vitals database resulted from project operations during the Phase 2 third data collection interval.

Data collection operatio ns for the Phase 2 third data collection in terval (3a and 3b) wer e conducted similar to the Phase 2 first and second data collection intervals described earlier in this report. Data was collected during the third Phase 2 data co llection interval retrospectively from monitors us ed in patien t care f or identif ied cases and was stored on portable m emory cards compatible with the M Rx m onitor as descr ibed f or the initial Phase 2 data collec tion interva l. SwRI and SA EMS collaborated continuously dur ing the period of opera tion to identify and evaluate cas es and to tr ansfer acquired ele ctronic m onitor data to th e SwRI data acquis ition laptop personal com puter (PC) for tem porary st orage. The data collected included digital physiologic parameter and digitally-sam pled waveform data files along w ith associated m onitor serial num ber, operational data , events, and tim es. No persona lly ide ntifiable inf ormation was included in this data.

As the f ield m onitor da ta collec tion work proc eeded, SwRI and SA EMS also collaborated to collect case run-sheets and patient care forms, as routinely generated during SA EMS operations, for identified candidate cases, wi th personally identif iable data deleted. Inform ation obtainable from these for ms inclu des the SA EMS seven digit case num ber assigne d to each cas e, th e unique un it num ber of the am bulance(s) d ispatched for the cas e, th e age of the patients (s) involved, the general type of inci dent involved, the hospital(s) re ceiving the patient(s), the date and time of the EMS 911 call, tim e of the EMS un it arrival at the scene, and tim e of EMS unit arrival at the receiving hospital.

Subtask 4.c Review and upgrade SwRI Trauma Vitals data process algorithms relative to developing data content.

During conduct of the third of the three planned data collection intervals for Phase 2, SwRI worked with SA EMS to access patient physiological data acquired using the MRx monitor during patient care and transport retrospectively for each identified patient. This was accomplished as described above for the first and second phase 2 data collection interval.

During conduct of the third Phase 2 data collection interval, two patient cases were encountered for which patients were triaged and cared for in the field by SA EMS but the patient was ultimately transported to a hospital by air helicopter services. For these patients, electronic pre-hospital physiological data acquired during the early ground care (first responder) interval of the case was collected and processed as described herein, and the resulting Trauma Vitals research data and case information was noted to reflect the ultimate air transport for the respective case. Research electronic pre-hospital patient data may be also collected within the respective helicopter service, and events such as this may provide an opportunity to merge electronic pre-hospital patient data collected during the early first responder ground care interval and the following helicopter-based care and transport interval to produce research data records spanning the combined intervals.

One SA EMS patient case was encountered during the Phase 2 third data collection interval that included information for multiple patients, and six SA EMS patient cases were encountered where multiple MRx monitor files were collected for each patient. The reasons for these case structures and their relationships to pre-hospital data collected for these cases were addressed in discussions for the initial and second Phase 2 data collection intervals.

Subtask 4.d Associate cases, process, and provide pre-hospital patient data to ISR.

In order to develop the desired research data, SwRI needed to accurately associate identified SA EMS qualifying patient case information with the appropriate electronic digital data files generated by the MRx monitor. This needed to be accomplished without availability of patient personally identifiable information within the records or files. These operations were conducted as described above for the first and second data collection intervals conducted during Phase 2.

During the extended Phase 2 third data collection interval (both intervals 3a and 3b), SwRI and SA EMS identified 182 candidate cases for data collection and processing for the subject study. SwRI and SA EMS operated to collect and process electronic monitor data for all of the 182 code 3 injury/trauma cases identified as candidates. During retrospective analysis, 22 cases were excluded from the study because it could not be established that the patients met age criteria for the subject study, because an accurate association between the respective SA EMS case records and electronic monitor files could not be adequately established, or because corrupted electronic data files were encountered during processing. Excluded cases were not further processed and respective data were discarded. For one case, two patients were cared for and transported by different SA EMS ambulances, due to injuries sustained in the same incident (same SA EMS case). For six cases, two monitor files were generated during pre-hospital care and transport of a single patient as described earlier in this report. Therefore, SwRI provided a total of 167 processed data files for use in the Trauma Vitals database, reflecting pre- hospital data acquired for 161 qualifying patients.

SwRI provided the electronic pre-hospital data for the 161 qualifying patients as processed for use in the Trauma Vitals database to USAISR. Also, the respective SA EMS run-sheets and patient care forms that were acquired during the Phase 2 third data collection interval, without personally identifiable information, were also provided to USAISR for use in the CCCE research program.

As described for the initial Phase 2 data collection interval, analysis relevant to the design of the subject study included timing analyses for qualifying cases for which patient pre-hospital data was collected and processed and ultimately provided for further research purposes. The IDD time interval was derived from date and time information contained in the SA EMS run-sheet and patient care form records and similar information contained within the respective electronic monitor files.

During Phase 1 of the subject study, a limited pre-hospital patient data collection interval was conducted, using a different monitor and a fraction of the ambulances operating in the SA EMS system. Timing analyses were conducted for the 25 qualifying cases encountered during the Phase 1 ground EMS data collection interval and for a random cohort of 57 qualifying cases transported to participating San Antonio Level 1 Trauma Centers by helicopter services. Collaborative comparative analyses by SwRI and USAISR demonstrated that, for these samples, the MIDD time value for the helicopter services was almost 15 minutes longer than the MIDD experienced by the ground SA EMS first responder system. Further analysis of the variances between the two data sets demonstrated a statistically significant difference between the two groups ($p<0.05$).

Similar analyses were conducted for combined pre-hospital patient data acquired during the second and third Phase 2 data collection intervals. For this larger data population of 209 qualifying patient cases, the MIDD experienced by the ground EMS first responder system during the Phase 2 second and third data collection intervals was 18.48 minutes, or 42 seconds, shorter (approximately 3.6% less delay) than the MIDD obtained during the initial Phase 2 ground EMS data collection interval (n=102) and 4.77 minutes shorter (approximately 20.5% less delay) than the MIDD experienced in the limited ground EMS Phase 1 (n=25) interval. Comparative analysis between the MIDD obtained during the Phase 2 combined second and third ground EMS collection intervals and the MIDD for the random cohort of cases transported by helicopter services showed that, for these samples, the ground EMS first responder services experienced a 19.5 minute shorter MIDD than the MIDD experienced by the helicopter services. Analysis of the variances between the two data sets demonstrated a statistically significant differences between the two groups ($p<0.05$). A summary of statistical values derived from analysis of the combined data collected during Phase 2 second and third data collection intervals working with ground EMS services and data collected within helicopter-based services is presented in Table 2. Data from this analysis are graphically presented as means ± standard deviation in Figure 2.

Table 2. Statistical Summary of Initial Data Delay Times for Air and Ground Services; Phase 2, Second and Third Data Collection Intervals Combined

	Ground EMS Service Phase 2, 2nd and 3rd Intervals (n=209); (hr:min:sec)	Helicopter Service (n=57);(hr:min:sec)	Δ=Gnd-Air (abs.val.) (hr:min:sec)
MIDD	00:18:29	00:37:59	00:19:30
Standard Deviation	00:06:45.0	00:19:34.8	00:12:49.8
Range	00:52:20	01:28:41	00:36:21
95% Confidence Interval Upper Bound	00:19:24	00:43:11	00:23:47
95% Confidence Interval Lower Bound	00:17:35	00:32:48	00:15:13

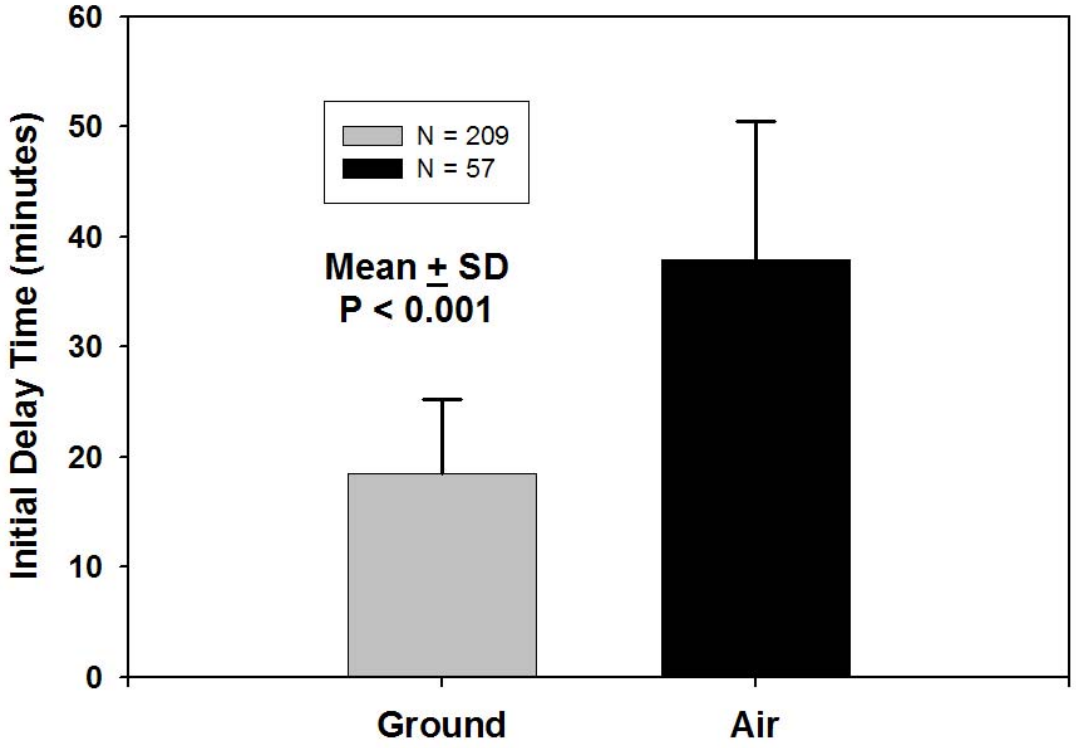

Figure 2. IDD Analysis Results; Phase 2 Ground EMS 2nd and 3rd Intervals Combined Compared to Helicopter Experience

Analysis of the data obtained during the Phase 2 initial data collection interval (n=102) and the Phase 2 second and third data collection intervals combined (n=209), both representing ground EMS system experience, was also conducted. Comparative analysis of the data from the Phase 2 initial data collection interval and the Phase 2 second and third (combined) data collection intervals demonstrated that, for these samples, there was not a statistically significant difference between the two data populations. However, a review of the analysis of the data collected during the Phase 2 extended third data collection interval showed a much greater range of IDD time values (52.3 minutes) than was found for the Phase 2 initial data collection interval (35.7

minutes). A summary of statistical values derived from analysis of the combined Phase 2 second and third data collection intervals and the Phase 2 initial data collection interval working with ground EMS services is presented in Table 3. Data from this analysis are graphically presented as means ± standard deviation in Figure 3.

Table 3. Statistical Summary of Initial Data Delay Times for Phase 2 Initial Data Collection Interval and Phase 2 Second and Third Data Collection Intervals Combined.

	Ground EMS Service Phase 2, 1st Interval (n=102); (hr:min:sec)	Ground EMS Service Phase 2, 2nd and 3rd Intervals (n=209); (hr:min:sec)	Δ=Phase 2 Int2&3-Int 1 (abs. val.) (hr:min:sec)
MIDD	00:19:11	00:18:29	00:00:42
Standard Deviation	00:06:46.4	00:06:45.0	00:00:01.4
Range	00:35:44	00:52:20	00:16:36
95% Confidence Interval Upper Bound	00:20:30	00:19:24	00:01:06
95% Confidence Interval Lower Bound	00:17:52	00:17:35	00:00:17

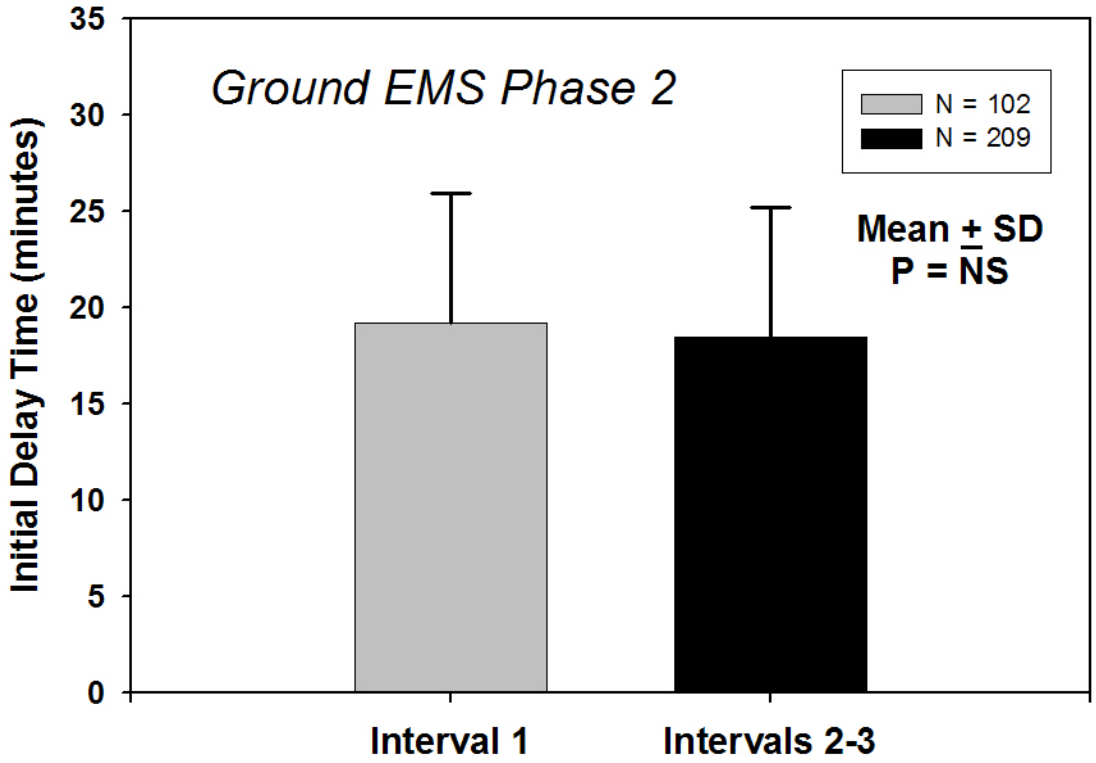

Figure 3. IDD Analysis Results; Phase 2 Initial Ground EMS Interval Compared to Combined 2nd and 3rd Intervals

A review of the data and related case run-sheets and patient care forms show that, for most cases, the delay in the onset of patient data collection (IDD) is a reflection of response time for the

closest available responding EMS unit at the time of the 911 call for help. In a small subset of cases, however, extended IDD times were found to occur for two major reasons. In some cases, a responding EMS unit can be delayed in obtaining access to a patient because an active unsecured crime scene (standoff or shooting in progress, for example) is encountered upon arrival of the EMS unit at the scene and the EMS crew must wait for law enforcement to secure the location and provide safe access to the patient. In other cases, the review noted that some longer IDD times were associated with difficult or protracted patient extraction from unstable or potentially dangerous conditions (patient trapped in crushed vehicle, for example) by responding law enforcement and firefighter crews before ground EMS crews can obtain access to the patient to begin providing pre-hospital care and assessment. A further review of such cases identified a single case encountered during operations for the Phase 2 second and third data collection intervals that presented an extremely long IDD time. This case involved an injured patient trapped inside a crushed, upside down vehicle that had fallen from a bridge and landed in a water area. Rescue teams eventually were required to retrieve and deploy special jacks, airbags, and shoring to raise and stabilize the vehicle. This enabled the teams to then cut away portions of the vehicle to gain access to the patient and facilitate extraction. The IDD time for this case was 57.05 minutes which is more than a factor of three greater than the MIDD for this case population and more than eight times the standard deviation for this population of samples.

For completeness, the comparative analysis on these samples was repeated after removing data related to the single case with atypically long IDD as described. This analysis demonstrated that, for these samples, there was not a statistically significant difference between the two data populations. For these samples, the data ranges were found to be essentially the same. A summary of statistical values derived from analysis of the combined Phase 2 second and third data collection intervals (with data for one atypical case removed) and the Phase 2 initial data collection interval working with ground EMS services is presented in Table 4. Data from this analysis are graphically presented as means ± standard deviation in Figure 4.

Table 4. Statistical Summary of Initial Data Delay Times for Phase 2 Initial Data Collection Interval and Phase 2 Second and Third Data Collection Intervals (One Atypical Ground EMS Case Removed) Combined

	Ground EMS Service Phase 2, 1st interval (n=102); (hr:min:sec)	Ground EMS Service Phase 2, 2nd and 3rd intervals (1 case removed: n=208); (hr:min:sec)	Δ=Phase 2 Int2&3-Int 1 (abs. val.) (hr:min:sec)
MIDD	00:19:11	00:18:18	00:00:53
Standard Deviation	00:06:46.4	00:06:13.0	00:00:33.4
Range	00:35:44	00:35:48	00:00:04
95% Confidence Interval Upper Bound	00:20:30	00:19:09	00:01:21
95% Confidence Interval Lower Bound	00:17:52	00:17:28	00:00:24

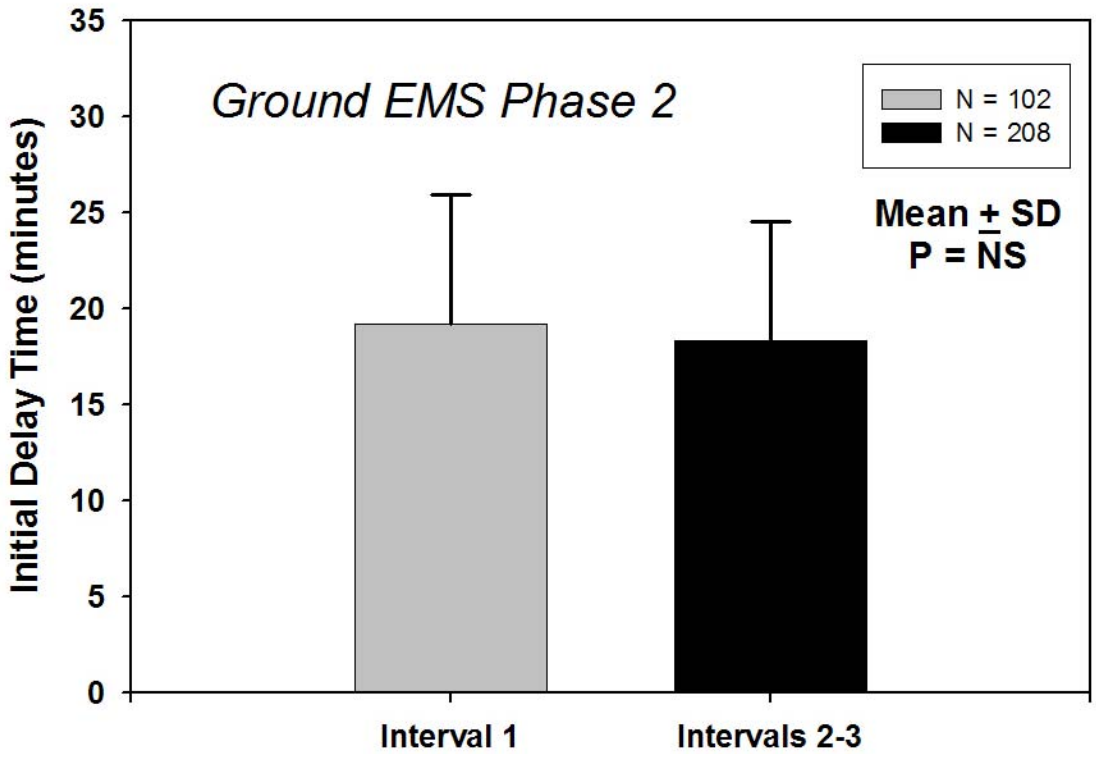

Figure 4. IDD Analysis Results; Phase 2 Initial Ground EMS Interval Compared to Combined (1 Atypical Case Removed) 2nd and 3rd Intervals

It is notable that data contai ned in Table 3 and Table 4 suggest tha t I DD tim e values were reduced (perhaps coarsely reflecting im proved ground EMS system ic response tim es) by approximately 5% during the tim e interval betw een operations for th e Phase 2 initial data collection interval (April, 2007) and the Phase 2 second and third data collection intervals (April-December, 2009), although this observation has not been thoroughly studied during this work.

Comparative analyses were conducted for the combined pre-hospital patient data acquired during all three Phase 2 data collection intervals ve rsus the random cohort of 57 qualifying cases transported to San Anton io Level 1 T rauma Centers by air se rvices as identified during Phase 1 of the subject project. F or this data popul ation of 311 qualifying ground EMS Pha se 2 patient cases, the MIDD experience during the three Phase 2 data collection intervals was 18.72 minutes. Further analysis between the MI DD obtained during the three Phase 2 ground EMS data collection intervals and the MIDD for the random cohort of cases transported by helicopter services showed that, for these samples, the gr ound EMS first responder services experienced a MIDD of slightly less th an half the MIDD experi enced by the helicopter services. Analysis of the variances between the two data sets dem onstrated a sig nificant difference between the tw o groups ($p<0.05$). A summary of s tatistical values derived from the analysis of the two data populations is presented in Table 5. Data from this analysis are graphically presented as means ± standard deviation in Figure 5.

Table 5. Statistical Summary of Initial Data Delay Times for Air and Ground Services; Phase 2, Three Data Collection Intervals Combined

	Ground EMS Service Phase 2, 3 Intervals (n=311); (hr:min:sec)	Helicopter Service (n=57);(hr:min:sec)	Δ=Gnd-Air (abs. val.) (hr:min:sec)
MIDD	00:18:43	00:37:59	00:19:16
Standard Deviation	00:06:45.3	00:19:34.8	00:12:49.5
Range	00:52:52	01:28:41	00:35:49
95% Confidence Interval Upper Bound	00:19:28	00:43:11	00:23:43
95% Confidence Interval Lower Bound	00:17:58	00:32:48	00:14:50

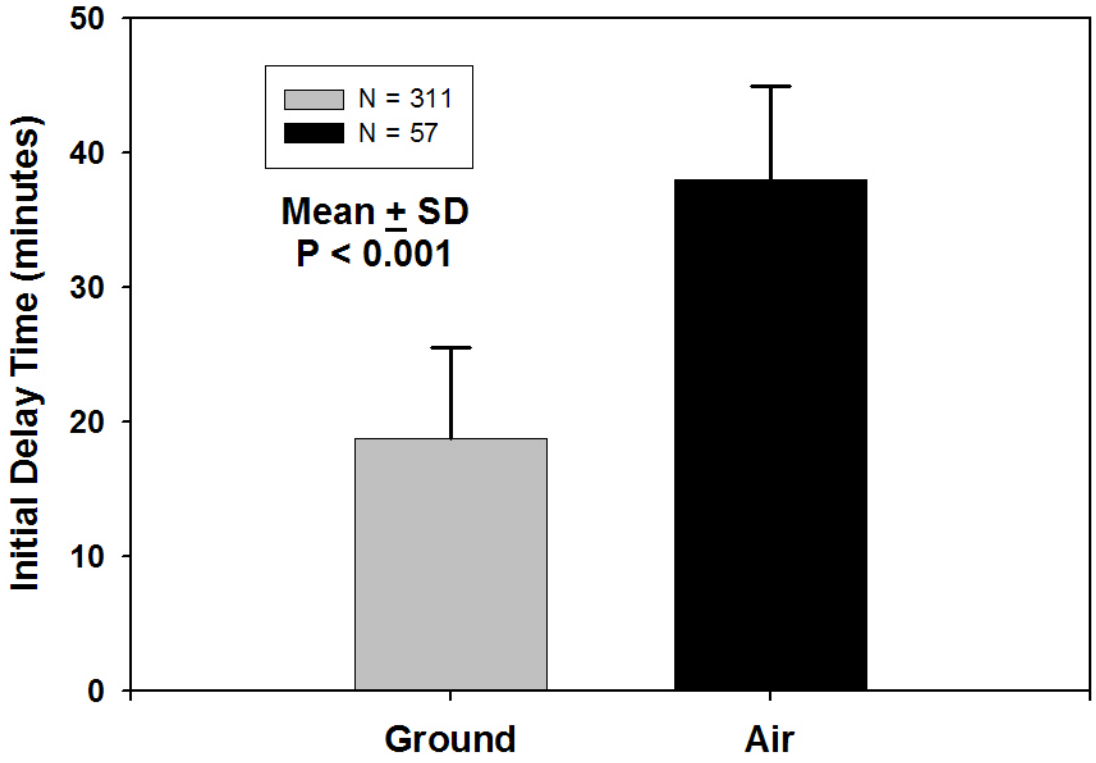

Figure 5. IDD Analysis Results; Phase 2 Ground EMS Intervals Combined Compared to Helicopter Experience

Finally, for completeness, the comparative analyses was repeated for the combined pre-hospital patient data acquired during the three Phase 2 data collection intervals, with data for the single extreme atypical case, as described above, removed versus the random cohort of 57 qualifying cases transported to San Antonio Level 1 Trauma Centers by air services. For this data population of 310 qualifying ground EMS Phase 2 patient cases, the MIDD experience during the combined three Phase 2 data collection intervals was 18.6 minutes. Further analysis between the MIDD obtained during the three Phase 2 ground EMS data collection intervals (one case

deleted) and the MIDD for the random cohort of cases transported by helicopter services demonstrated that, for these samples, the ground EMS first responder services experienced a MIDD of less than half the MIDD experienced by the helicopter services. Analysis of the variances between the two data sets showed a significant difference between the two groups ($p<0.05$). A summary of statistical values derived from the analysis of the two data populations is presented in Table 6. Data from this analysis are graphically presented as means ± standard deviation in Figure 6.

Table 6. Statistical Summary of Initial Data Delay Times for Air and Ground Services; Phase 2, Three Data Collection Intervals Combined (One Atypical Ground EMS Case Removed)

	Ground EMS Service Phase 2, 3 Intervals (1 case removed: n=310); (hr:min:sec)	Helicopter Service (n=57);(hr:min:sec)	Δ=Gnd-Air (abs. val.) (hr:min:sec)
MIDD	00:18:36	00:37:59	00:19:23
Standard Deviation	00:06:24.2	00:19:34.8	00:13:10.6
Range	00:36:20	01:28:41	00:52:21
95% Confidence Interval Upper Bound	00:19:18	00:43:11	00:23:53
95% Confidence Interval Lower Bound	00:17:53	00:32:48	00:14:55

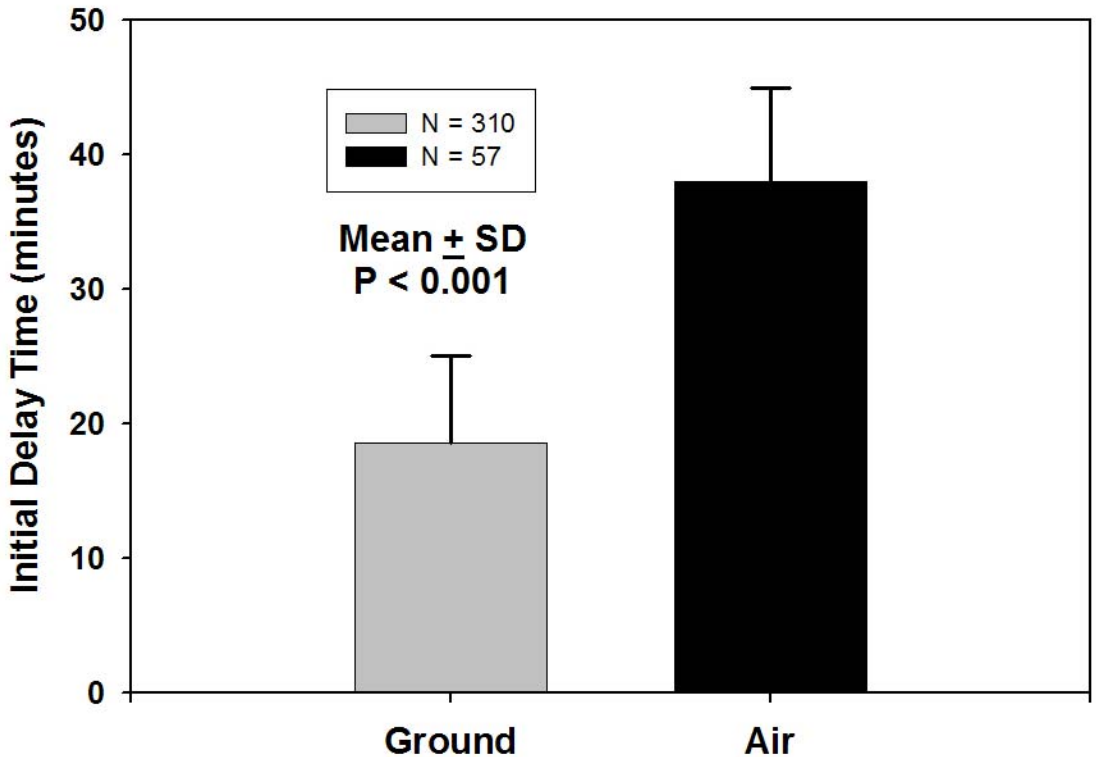

Figure 6. IDD Analysis Results; Phase 2 Ground EMS Intervals (1 Atypical Case Removed) Combined Compared to Helicopter Experience

The significance of the shorter IDD experienced in the ground EMS system is that physiological data reflecting parametric measurements and trends for severely injured patients begins sooner after an injury. For these samples, the mean delay in the start of patient pre-hospital data collection for helicopter-based services was more than twice as long as the MIDD experienced by the ground EMS study. The clinical significance of earlier post-injury onset of data capture for code 3 trauma patients within the Advanced Capabilities for the Combat Medic program will continue to be investigated by USAISR and SwRI in future work.

PHASE 2 (initial award)

TASK 3 Investigate improved mobile remote ultrasound techniques.

mapped to

PHASE 2 (modified)

TASK 5 To Investigate Improved Mobile Ultrasound Techniques.

This task was identified and included in the Phase 2 project plans to enable continuation of support and consultation by SwRI for research activities undertaken by staff at BAMC, Department of Emergency Medicine and Cardiology Service. Previous work, not related to the subject project, included demonstration and study of the utility and merit of transmission of images produced by portable diagnostic ultrasound devices from a moving ambulance to a remote hospital for real-time diagnostics support [1]. The communications capability that enabled these demonstrations and trials was provided by the LifeLink mobile telemedicine system and

satellite and mobile wireless transmission deployed in San Antonio[2-4]. SwRI planned to continue to coordinate with SA EMS to provide access to a project ambulance to accommodate one or two one-day sessions of demonstrations or trials under the subject subtask.

SwRI continued frequent discussions with relevant research staff from BAMC to discuss concepts for continuing research opportunities on this subject during Phase 2; however, additional research demonstration and trial opportunities within the subject area were not identified. Potential trials and demonstrations regarding real-time remote transmission of 12-lead cardiac electrocardiograph waveforms from a moving ambulance to a hospital facility, enabling research on the feasibility and merit of remote real-time diagnostics became a subject of interest to this collaborative team during discussions. This subject was judged to be outside the established scope of the subject task, and portable devices capable of providing suitable real-time output signals and suitable data receiver and presentation equipment for such trials were not available.

Key Research Accomplishments

- Pre-hospital electronic physiological monitor data and corresponding SA EMS run-sheets and patient care forms, with personal identifying information deleted, for 311 qualified patient cases were acquired during conduct of the three planned Phase 2 data collection intervals. Pre-hospital patient physiological data for each of these cases was processed by SwRI to be compatible in content and format with the Trauma Vitals research database used in the USAISR CCCE program. Processed pre-hospital physiological data, SA EMS case run-sheets, and patent care forms, with personal identifying information deleted, were provided to USAISR in support of CCCE research programs.
- IDD data acquired during Phase 2 of this study within the ground EMS system (SA EMS) and IDD data resulting from pre-hospital data collection operations within air services were subjected to comparative statistical analyses. The results of this work show that much shorter IDD times are achievable for pre-hospital patient data collected within ground EMS systems (see Reportable Outcomes section). These results are consistent with experience gained during limited previous Phase 1 ground EMS data collection operations.
- Advancements in data conversion were accomplished based on research of the MRx monitor data systems and lessons learned during the expanded data collection and processing operations during Phase 2. Additional modifications to the special data processing algorithms were accomplished to adapt to changed monitor data file content and structure as provided by the MRx physiological monitor. These changes were due to an interim upgrade of the operational firmware that was implemented in the fleet of SA EMS monitors after the initial Phase 2 data collection interval was completed. The special data processing algorithms are used for extracting and for matting patient physiological data records and relevant monitor configuration and operations information provided by the MRx monitor currently in use by the SA EMS system. The raw files containing relevant patient physiological data are processed and organized into XML reports containing content and formatting usable by the CCCE program. The algorithms also read and process embedded case timing information to facilitate case association and case timing analysis.
- SwRI researched and developed methodologies for accurate association between pre-hospital electronic monitor data files and EMS organizational case files, without personally identifiable information. Particularly, the SwRI and SA EMS team developed procedures

using encrypted case labeling and start times displayed for case files stored in the MRx monitor to accomplish more accurate case association at the time of data extraction from the monitor. This resulted in fewer "false" data files being collected and requiring retrospective examination. These improvements in data collection and processing methods were implemented to more efficiently and accurately coordinate electronic monitor data files and SA EMS case summary information, without the availability of personally identifiable information.

- Special algorithms for extraction and acquisition of electronic data files from the MRx monitor in SA EMS field operations were updated and improved. These developments included automatic labeling of respective electronic folders and files containing pre-hospital patient data to help facilitate coordination between data collection efforts and routine SA EMS operations and reporting, without the use of personally identifiable information.
- SwRI and SA EMS described a path forward for automatic and transparent retention and preservation of raw MRx monitor data within the planned future rollout of the SA EMS electronic case data system. Commercially available EMS database products often modify or discard raw physiological data during the process of producing efficiently stored NEMSIS-compliant case reports. However, the raw monitor data files are needed to facilitate retrospective extraction of pre-hospital patient data usable in the USAISR Trauma Vitals database, as well as retrospective in-depth case reviews. SwRI worked with the manufacturer of the MRx monitor and the developer of the EMS data management system planned for use in the future SA EMS electronic case data management system to maintain visibility and focus on the retention and preservation of the raw monitor data within these systems.

Reportable Outcomes

- Pre-hospital physiological data was collected for 358 potentially qualifying code 3 trauma patient cases that were cared for and transported to Level 1 trauma centers by the entire fleet of SA EMS system operating 24/7 during the three planned Phase 2 data collection intervals of the subject program. SA EMS run-sheets and case forms for these cases, without personally identifiable information, were also acquired for each of these cases during this work. Data from this population of cases was examined and processed to exclude patient records that were found to not qualify for inclusion in the subject study. The collected data was also processed to assure accurate association between electronic monitor data records and identified cases in the population. Data records for cases that did not qualify for use in the subject study or for which accurate association between the electronic records and SA EMS run-sheet and patient care form information could not be established were discarded. The remaining electronic patient data was processed to conform to the needs of the CCCE Trauma Vitals database. Electronic monitor data of suitable content and format for use in the USAISR programs and related SA EMS run-sheets and patient care forms, with personally identifiable information deleted, for 311 qualifying patient cases was provided to USAISR in support of CCCE research programs during Phase 2.
- The IDD was determined for the 311 qualifying ground SA EMS patient cases for which data was collected during Phase 2. The IDD is defined as the elapsed time interval between estimated time-of-injury and the onset of acquisition of pre-hospital patient physiological data for each qualifying case. Data sets from the 311 qualifying ground SA EMS patient cases and from a random cohort of 57 qualifying cases transported to participating San

Antonio Level 1 trauma centers by air services were analyzed. Comparative analysis of the two data sets by SwRI and USAISR demonstrated that the helicopter service experienced a MIDD greater than twice the MIDD experienced by the ground EMS first responder system. Analysis of the variances between the two data sets showed a significant difference between the two groups ($p<0.05$). The operational significance of the shorter IDD experienced in the ground EMS system is that physiological pre-hospital patient data acquisition begins significantly sooner after an injury in the ground system. For these samples, the mean delay of the beginning of data acquisition (MIDD) within the helicopter services was 37.98 minutes, or 19.27 minutes longer than the mean delay (18.72 minutes) experienced within the ground EMS system.

- A firmware upgrade program for all the monitors used by SA EMS occurred during Phase 2. This required adaptations and improvements for specially developed algorithms for extracting and processing raw pre-hospital physiological digital data for qualifying cases, as acquired in SA EMS operations, and for processing the raw data to produce data content and formats needed by the CCCE program during Phase 2.
- Methods for field acquisition and preliminary case identification, without personally identifiable data available, were improved during Phase 2. This methodology was designed to aid in field operations and to provide more efficient and accurate retrospective association between pre-hospital electronic monitor records and SA EMS case records for qualifying cases.
- Work to coordinate project data needs with evolving hardware and software data management capabilities and the developing SA EMS electronic case data system progressed. The need to retain and preserve raw monitor data during routine case data records operation was established during Phase 2 and is reflected in planning for future SA EMS routine operations and organizational data management.
- SwRI continued to develop a new initiative, the Parameter-based Remote Objective Pre-Hospital Emergency Triage (PROPHET) program, to support and expand data collection and research operations for pre-hospital medical care and decision-support technologies.
- Required list of persons receiving pay from this project:
  - Aguilar, John
  - Bartels, Keith
  - Bielke, Peggy
  - Dore, Monica
  - Downing, Karen
  - Gordon, Donald
  - Grant, Kimberly
  - Kinkler Jr., Ernest, S
  - Lents, Danny
  - Magee, Michael
  - Moczygemba, Mark
  - Rudewick, Todd
  - Rusk, Sherry
  - Thompson, Travis
  - Tong, David

- Whipple, John
- Williams, Kari

Conclusions

The U.S. Army's CCCE program includes research elements aimed at advances in triage, treatment, and field decision support systems. Ultimately, knowledge gained from such research could be of benefit to injured patients and care providers in many different types of settings, military and civilian, and especially in mass-casualty situations.

Physiological data and trending that can be acquired during the pre-hospital interval of care for seriously injured patients is sought in support of research activities that could yield meaningful advancements in triage and treatment of combat casualties in the field. Typically, helicopter-based patient transport systems have provided relatively focused opportunities for pre-hospital access to seriously injured patients for which the data of interest could be collected. This project is focused on exploring the feasibility and advantages of acquiring such data while working within a large municipal ground-based EMS system. The design of this study is based on the premise that pre-hospital patient data acquisition opportunities will typically begin much earlier in an injury event within a ground EMS first responder system than with helicopter-based services.

The nature of the CCCE program suggests that data reflecting a patient's physiological response to serious injury, beginning as soon as practical after the injury event, could be advantageous in the research program. Analysis of the data acquired during Phase 2 of the subject project shows that ground EMS first responder systems can provide the "soon as practical" opportunity for acquisition of desired data. Also, the large volume of injury cases typically handled by a large municipal ground EMS system suggests that a relatively high rate of cases of interest could be available to help meet the data needs of the CCCE program, and the data reported herein reflect a relatively large number of cases encountered during the three data collection periods planned for Phase 2.

The three planned one-month data collection intervals, working with SA EMS, and the related data processing and analysis were accomplished during Phase 2 of the subject project. During conduct of the second and third data collection intervals, the number of cases identified as potentially qualifying cases for this project was observed to be fewer than expected for the time periods involved. This observation was found to correlate with changes in organizational operations within SA EMS and more conservative efforts by project staff to accurately select cases for the subject project that would ultimately qualify for inclusion in the study. The lower than anticipated rate of subject case identification during the data collection intervals was not associated with a lower rate of trauma cases encountered by the SA EMS system during those times. The third of the three planned data collection intervals was extended in order to identify and obtain pre-hospital patient data for additional cases, in an attempt to reach the goal of 300 anticipated cases during Phase 2 operations. Phase 2 efforts resulted in case identification, pre-hospital data collection, data processing, and provision of pre-hospital patient physiological data files to USAISR for 311 qualifying patients. The mean delay between the estimated time of injury and the onset of pre-hospital patient data acquisition (MIDD) for this population of patient cases was 18.6 minutes (with data for one extraordinary case removed (n=310)), and 18.72 minutes with data for the one extraordinary case included (n=311). These MIDD values were

compared to the MIDD experience for a random cohort of cases within helicopter-based services transporting patients to the same hospitals. For the helicopter-based services, the MIDD of 37.98 minutes was approximately twice the delay experienced within the ground EMS system. Also, the rate of qualifying cases encountered, and for which data was collected, during the ground EMS operations interval was much higher than available within air services.

These findings support the goals of this study and also add significantly to the pre-hospital patient data otherwise available in the Trauma Vitals database in two important areas:

1. The patient data collected and processed during Phase 2, working within the ground EMS first responder system, reflects a data start time occurring much earlier in injury events than data acquired within helicopter-based services. This provides the opportunity to observe and research parameters and trends of interest occurring in a relatively early time window compared with data collected during helicopter-based operations. The "earlier window" of patient data acquired within ground operations can be viewed as complementary to the "later window" of data that can be acquired during air operations. Data from the two modes of operations combined could provide a more complete picture of the parameters of interest than data from either mode alone.
2. The inclusion of data collected within the ground EMS system reflects a large increase in the volume of qualifying cases for which pre-hospital patient data can be acquired during a given time interval. This finding reflects an opportunity to dramatically increase the research patient population in the Trauma Vitals database.

During Phase 2, SwRI planned to integrate more efficient and transparent (within SA EMS operations) preservation and collection of needed pre-hospital data in support of the CCCE program during future SA EMS operations. These improvements in research data collection were planned to be integrated during the Phase 2 second and third data collection intervals with incremental milestones in the planned enhanced capabilities within SA EMS. These milestones included near-automatic wireless transfer of patient physiological data, as acquired and stored by the monitor during patient care, for further processing and inclusion in the planned SA EMS electronic case data management system. SwRI worked with SA EMS and the suppliers of the monitor and the EMS medical records database products to assure preservation of raw monitor data files during this process to enable future retrospective availability of patient pre-hospital data of interest to the subject project. Significant manufacturer delays in development and release of planned data management capability upgrades for the physiological monitor and commercial database products compatible with the monitor, as intended for use in planned enhancements for the SA EMS electronic case data management system, were experienced during Phase 2 of the subject study. This issue impacted the planned integration of later, more efficient and transparent (Phase 2 second and third data collection intervals) research data collection operations and routine SA EMS case data management capabilities. Subject to continuing manufacturer delays in development of monitor data management tools and the resulting schedule impact on the planned rollout of the monitor data acquisition aspects of the electronic case data management system within SA EMS, SwRI began planning and preparations to exercise contingency plans for data collection during Phase 2 of the project. The contingency plans were included as special considerations in the description of the approved Phase 2 SOW. The contingency plans included moving forward with conduct of remaining planned data collection intervals independent of the evolving, but delayed, rollout of SA EMS routine monitor data acquisition and processing operations. SwRI began preparations for conduct of the

remaining two planned patient data collection intervals, using essentially the same methods used during the initial data collection interval. This was done in order to assure completion of planned operations for the two remaining data collection intervals and completion of processing and provision of the target patient data to USAISR within prevailing cost and schedule terms of the project.

Finally, SwRI plans to continue future work (not part of the subject project) to develop an initiative to include future automation, expansion, and extension of the data collection and CCCE research. Future plans for the PROPHET program include refinement, automation, extension, and expansion of the data collection and research efforts. Additional research components are planned to further analyze collected data to help identify meaningful predictive trends and algorithms and to expand data gathering and research work to include additional potential field triage and other pre-hospital medical advances. It is anticipated that this work will ultimately lead to deployable prototype equipment, field and clinical trials, and development/distribution of the technologies to military as well as civilian casualty care organizations.

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3. Strode CA, Rubal BJ, Gerhardt RT, Christopher FL, Bulgrin JR, Kinkler ES, Bauch TD, Boyd SYN: Distance-Unlimited Focused Abdominal Sonography for Trauma (FAST) Using Wireless, Satellite, and Mobile Ambulance Transmissions [abstract], Prehospital Emergency Care Jan/Mar 2003;7(1):165
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